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EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503-0001

Tuesday, June 2, 1998

LEGISLATIVE REFERRAL MEMORANDUM

TO:	Legislative Liaison Officer - See Distribution below
FROM:	Janet R. Forsgren (for) Assistant Director for Legislative Reference
OMB CONTACT:	Robert J. Pellicci PHONE: (202)395-4871 FAX: (202)395-6148
SUBJECT:	**HHS Fact Sheets on HR3052 Safety of Imported Food Act of 1997**
DEADLINE:	**1:00 p.m. Wednesday, June 3, 1998**

In accordance with OMB Circular A-19, OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President. **Please advise us if this item will affect direct spending or receipts for purposes of the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.**

COMMENTS: The attached FDA-prepared fact sheets are designed to illustrate the benefits of enhanced FDA food import authority. These one-pagers would be distributed to congressional staff.

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LRM ID: RJP280 **SUBJECT:** HHS Fact Sheets on HR3052 Safety of Imported Food Act of 1997

RESPONSE TO
LEGISLATIVE REFERRAL
MEMORANDUM

If your response to this request for views is short (e.g., concur/no comment), we prefer that you respond by e-mail or by faxing us this response sheet. If the response is short and you prefer to call, please call the branch-wide line shown below (NOT the analyst's line) to leave a message with a legislative assistant.

You may also respond by:
(1) calling the analyst/attorney's direct line (you will be connected to voice mail if the analyst does not answer); or
(2) sending us a memo or letter
Please include the LRM number shown above, and the subject shown below.

TO: **Robert J. Pellicci Phone: 395-4871 Fax: 395-6148**
Office of Management and Budget
Branch-Wide Line (to reach legislative assistant): 395-7362

FROM: _____ **(Date)**

_____ **(Name)**

_____ **(Agency)**

_____ **(Telephone)**

The following is the response of our agency to your request for views on the above-captioned subject:

_____ **Concur**

_____ **No Objection**

_____ **No Comment**

_____ **See proposed edits on pages** _____

_____ **Other:** _____

_____ **FAX RETURN of** ____ **pages, attached to this response sheet**

Benefits of Enhanced FDA Import Authority
Example of Microbial Contamination of Imported Soft Cheeses

The Situation:

In 1983, several outbreaks of gastrointestinal illness affecting in Washington, DC, Illinois and Wisconsin were associated with the consumption of Brie, a type of soft cheese produced in France. Unlike processes in the U.S., many soft cheeses in France are produced using non-pasteurized milk. FDA analysis revealed high levels of *Escherichia coli*, an indication of insanitary practices, in many soft cheeses imported from France. FDA initiated detention actions against products from the individual firms responsible for the contamination. In 1986 and 1987, numerous recalls of Brie cheese from France were initiated by FDA due the presence of a pathogen, *Listeria monocytogenes*. *Listeria monocytogenes* can be serious and sometimes fatal to the very young, the old and those with weakened immune systems. It may also cause miscarriage and stillbirths in pregnant women. *Listeria monocytogenes* is not controlled by refrigeration, unlike other bacteria, in that it grows at normal refrigeration temperatures. During this time frame, FDA also documented microbial contamination of soft cheese from other European countries. In 1986, 71 samples of soft cheese from Italy were analyzed and 26.8% were found to be contaminated with *Listeria monocytogenes* or *Escherichia coli*.

The Problem:

Because they are made from non-pasteurized milk, soft cheeses from France and other several European countries had high potential for adverse health effects from microbial contamination. FDA therefore issued an import alert in February 1987 placing all soft cheeses from France and selected manufacturers from other countries on detention without physical examination. The only exception was for soft cheeses from France that were certified by the French government under an agreement with FDA. The agreement required soft cheeses to be produced using pasteurized milk and in accordance with good manufacturing practices aimed at prevention of microbial contamination.

Benefit Under the Proposed Legislation:

Under existing authority, FDA is obligated to consider each shipment-specific certification. Under the proposed legislation, FDA would have an additional enforcement tool permitting denial of entry to food when the Secretary has determined that the exporting country's systems, conditions, and measures do not achieve the U.S. level of protection for the commodity in question. Except for French certified cheeses, FDA had such information and would have been able to make a determination that soft cheeses from other countries in Europe would have been deemed adulterated, and denied entry. This determination would have prevented illnesses and allowed for a better allocation of resources by reducing the need for FDA inspection of product from country(ies) determined to not provide our level of protection. A preventive determination could create an incentive for the European governments and cheese producers to upgrade their food safety systems and requirements.

Benefits of Enhanced FDA Import Authority
Example of Cyclospora on Raspberries From Guatemala

The Situation:
In the spring of 1997, multiple *Cyclospora* outbreaks affecting approximately 7,000 people, were traced to imported raspberries. *Cyclospora* is a newly recognized protozoan parasite that infects the human digestive tract causing gastrointestinal distress, including prolonged diarrhea. The pathogen is transmitted by ingestion of water or food contaminated with *Cyclospora*. Other symptoms include loss of appetite, weight loss, bloating, stomach cramps, nausea, vomiting, tiredness, muscle aches, and low grade fever.

The Problem:
Cyclospora is extremely difficult to detect microscopically, except in the stage of its life cycle when it is present in stool samples. Consequently, epidemiologists can only trace the source of infection through meticulous questioning of the victims to determine the common food that may have caused the infection and then trace the food back to its place of origin.

CDC, working in collaboration with FDA, epidemiologically linked raspberries from Guatemala as the common food that caused the illnesses. FDA then initiated a major effort to examine a large number of berry shipments from Guatemala in an attempt to identify the source(s) of the contamination. Because of the inability to find the organism in raspberries, FDA was hindered severely in its ability to control the import of the suspect berries. Despite one year of intense effort by FDA working with the Guatemalan raspberry producers, the problem remains unresolved.

Benefit Under the Proposed Legislation:
Under existing authority, because testing methods were unable to find the problem organism on the raspberries, FDA did not believe it appropriate to detain shipments of Guatemalan raspberries based solely on preliminary epidemiological data that only suggested raspberries as the problem. FDA was obligated to sample and analyze numerous shipments in an attempt to demonstrate that the parasite was present on raspberries. Under the proposed legislation, FDA would have an additional enforcement tool permitting denial of entry to food when the Secretary has determined that the exporting country's systems, conditions, and measures do not achieve the U.S. level of protection for the commodity in question. FDA had such information regarding the conditions of production for Guatemalan raspberries and would have been able to make a determination such that all raspberries from Guatemala would have been deemed adulterated, and denied entry. This determination would have prevented several hundred illnesses and allowed for a better allocation of resources by reducing the need for FDA inspection of product from a country determined to not provide our level of protection. A preventive determination could create an early incentive for the Guatemalan government and raspberry growers to upgrade their food safety system.

Benefits of Enhanced FDA Import Authority

Staphylococcal Enterotoxin in Canned Mushrooms from China and Other Countries

The Situation:

In 1989, there were four confirmed outbreaks of staphylococcal food poisoning attributed to canned mushrooms processed in the Peoples Republic of China (PRC) affecting 112 people. Staphylococcal food poisoning comes from a toxin produced by the *Staphylococcus* bacteria. Symptoms are nausea, vomiting, diarrhea, abdominal pains, headaches, muscular cramping and, on rare occasions, death. Subsequent sampling and analysis of imported Chinese mushrooms by FDA found staphylococcal enterotoxin (SE) in canned mushrooms processed by nine factories located in six PRC provinces. FDA also found SE in canned mushrooms from Korea, Hong Kong, Thailand and Malaysia, but using the same brined mushrooms that are the source of the problem and originating in the PRC.

The Problem:

FDA found SE in mushrooms processed by 14 of 79 registered canners which are located in 7 of the 12 provinces that process mushrooms. Due to the apparent widespread contamination in the PRC canning plants and the serious nature of the toxin, in October 1989 all canned mushrooms from the PRC were placed under detention without physical examination. Shipments of such mushrooms could not enter the United States unless they were accompanied by documentation from acceptable third party experts demonstrating the absence of SE. The nine year process has been extremely resource intensive for FDA and the current "lot-by-lot release" arrangement remains burdensome.

Benefit Under the Proposed Legislation:

Under existing authority, FDA is obligated to consider each shipment-specific certification. Under the proposed legislation, FDA would have an additional enforcement tool permitting denial of entry to food when the Secretary has determined that the exporting country's systems, conditions, and measures do not achieve the U.S. level of protection for the commodity in question. FDA had such information and could have been able to make a determination that all canned mushrooms from the PRC and other Asian countries using contaminated brined mushrooms from the PRC could have been deemed adulterated under the proposed legislation, and denied entry. This preventive determination would have prevented illnesses and allowed for a better allocation of resources by reducing the need for FDA inspection of product from a country determined to not provide our level of protection. A preventive determination could create an incentive for the PRC government and mushroom producers to upgrade their food safety system.

Benefits of Enhanced FDA Import Authority
Example of Illegal Use of Pesticides in Snow Peas from Guatemala

The Situation:
Since the late 1980's, FDA surveillance monitoring of snow peas from many growers in Guatemala routinely found residues of chlorothalonil (a fungicide) and methamidophos (an insecticide) for which there are no established residue tolerances in the United States. Despite FDA actions against individual producers, the problems continued unabated with the number of firm-specific detentions increasing as the number of snow pea shipments from Guatemala increased.

The Problem:
In 1992, in an attempt to stem the flow of illegal shipments, FDA placed all snow peas from Guatemala on detention without physical examination. The Guatemalan Snow Pea Committee, an industry and government consortium, developed and implemented an export certification program with features that included control of pesticide usage at farm level among the hundreds of individual snow pea producers, and export controls including sampling and analysis of each exported shipment. Despite genuine efforts in Guatemala exemplified by these programs, it became clear through FDA audit sampling and review of analytical data from private laboratories that the problem was continuing and that authorities in Guatemala could not prevent the misuse of the pesticides.

Under its existing authority, FDA could have detained individual shipments based on an "appearance" of adulteration, but it was obligated to allow shipments of snow peas into the country if the shipment was accompanied by acceptable documentation demonstrating its compliance. FDA, therefore, was forced to retain the burden of reviewing shipment-specific documentation from laboratories attesting to such compliance. Review of such paperwork, which included laboratory data sheets and sample integrity documents, is resource intensive.

Benefit Under Proposed Legislation:
Under existing authority, FDA is obligated to consider each shipment-specific certification. Under the proposed legislation, FDA would have an additional enforcement tool permitting denial of entry to food when the Secretary has determined that the exporting country's systems, conditions, and measures do not achieve the U.S. level of protection for the commodity in question. FDA had such information and would have been able to make a determination that all snow peas from Guatemala would have been deemed adulterated, and denied entry. This determination would have allowed for a better allocation of resources by reducing the need for FDA inspection of product from a country determined to not provide our level of protection. A preventive determination could create an incentive for the Guatemalan government and snow pea growers to upgrade their food safety system.

Benefits of Enhanced FDA Import Authority
Example of Filth and Decomposition in Shrimp from India

The Situation:
In early 1979, FDA sampling and analyses revealed a high violation rate in fresh or fresh frozen Indian shrimp for filth and decomposition. While no illnesses were traced to this product, decomposed shrimp can result in a severe allergic reaction to histamine. FDA issued an import alert, placing all shrimp from India under detention without physical examination. Under the alert, no shrimp from India could enter the United States unless it was accompanied by acceptable documentation demonstrating the absence of filth and decomposition.

The Problem:
In response to the situation, the Indian shrimp industry, along with the Indian government, proposed a shipment-specific control program to prevent the safety and sanitation problems for shrimp exported to the United States. In January 1980, a certification program was implemented by FDA and the Indian government that allowed the Indian government to certify compliance with FDA requirements. Indian officials assured FDA that stringent shipment-specific testing and improvements in export controls were implemented by the Indian government. FDA conducted audit sampling of shrimp and occasional review of laboratory results provided by Indian authorities. FDA repealed the certification program in 1992 after an audit and surveillance sampling program demonstrated a high violation rate in Indian shrimp for filth, and decomposition.

Benefit under the Proposed Legislation:
Under existing authority, FDA is obligated to consider each shipment-specific certification. Under the proposed legislation, FDA would have an additional enforcement tool permitting denial of entry to food when the Secretary has determined that the exporting country's systems, conditions, and measures do not achieve the U.S. level of protection for the commodity in question. FDA had such information and would have been able to make a determination that shrimp imported from India would have been deemed adulterated, and denied entry. This determination would have allowed for a better allocation of resources by reducing the need for FDA inspection of product from a country determined to not provide our level of protection. A preventive determination could create an incentive for the Indian government and shrimp producers to upgrade their food safety system.